IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of	)	Docket No.: 36357
	)	
WHITSON, Debi	)	Group Art Unit: 3626
	)	
Serial No.: 09/802546	)	Examiner: PORTER, Rachel L.
	)	
Filed: 03/09/2001	)	Confirmation No.: 8651
	)	
Title: PROCESS OF INTERFACING A PATIENT DIRECTLY WITH THEIR OWN ELECTRONIC MEDICAL RECORDS	)	Customer No.:

APPEAL BRIEF

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

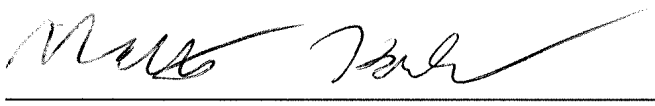
Application of	)	Docket No.: 36357
	)	
WHITSON, Debi	)	Group Art Unit: 3626
	)	
Serial No.: 09/802546	)	Examiner: PORTER, Rachel L.
	)	
Filed: 03/09/2001	)	Confirmation No.: 8651
	)	
Title: PROCESS OF INTERFACING A PATIENT DIRECTLY WITH THEIR OWN ELECTRONIC MEDICAL RECORDS	)	Customer No.:

APPELLANT'S BRIEF ON APPEAL

In response to the Final Office Action dated February 28, 2007, and the Notice of Appeal filed March 15, 2007, Appellant's Brief on Appeal in accordance with 37 C.F.R. § 41.37 is hereby submitted. The Examiner's rejections of claims 1, 4, 6, 18, and 20 as last amended are herein appealed, and allowance of said claims is respectfully requested.

The requisite fee of $250.00 as required by 37 C.F.R. § 41.20 accompanies this Brief. Any additional fee which is due in connection with this Brief should be applied against Deposit Account No. 19-0522.

Respectfully submitted,

By 

Matthew P. Harlow, Reg. No. 52,994
HOVEY WILLIAMS LLP
2405 Grand Boulevard, Suite 400
Kansas City, MO 64108
(816) 474-9050

ATTORNEYS FOR APPELLANT

Following are the requisite statements under 37 C.F.R. § 41.37:

I. Real Party in Interest

Debbie Whitson is the inventor of the claimed invention. Debbie Whitson has not assigned any of her rights, title, or interest in the invention, application, or any Letters Patent issuing therefrom to any other person or entity. Therefore, Debbie Whitson is the real party in interest.

II. Related Appeals and Interferences

No related appeals or interferences are known to the Appellant which may directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

III. Status of Claims

This application was filed on March 9, 2001, with 17 claims, of which claim 1 was independent. Claims 18–21 were added in an amendment dated July 5, 2005, with claims 18 and 20 being independent. Claims 3, 8, 12, and 15–16 were subsequently cancelled. Therefore, claims 1–2, 4–7, 9–11, 13–14, and 17–21 are currently pending with claims 1, 18, and 20 being independent. The Examiner's rejections of claims 1, 4, 6, 18, and 20 as last amended are herein appealed.

IV. Status of Amendments

No amendments have been filed subsequent to final rejection.

V. Summary of Claimed Subject Matter

The invention of claim 1 is a process of allowing a patient to have limited input access to their electronic medical record. The process includes providing the patient (1) with a machine readable card (3) including a questionnaire concerning the patient's medical history, environment, symptoms, or other pertinent information for answering by the patient (1). (Application, page 5, lines 14–18; page 8, lines 5–19). The machine

readable card (3) is interfaced with a scanning type machine (11) to convert the patient's written answers to a data stream (Application, page 6, lines 1–7; page 9, line 17–page 10, line 6). The data stream is arranged into a defined data structure simulating the protocol structure (15) from a party having authorization to export data to the patient's patient-specific electronic medical record (Application, page 5, line 19–page 6, line 11; page 10, lines 3–8). The formatted data is sent to an assigned location for importing into the patient's patient-specific electronic medical record, wherein the patient's electronic medical record contains patient-specific, clinical information regarding the patient's health (Application, page 5, line 24–page 6, line 7; page 10, lines 9–19).

According to the invention of dependent claim 4, the machine readable questionnaire (3) includes questions concerning the systems making up the human body with designated locations for patient responses (Application, page 8, lines 8–15).

According to the invention of claim 6, the data stream is converted and arranged to a defined set of data structures simulating the protocol of Health Level Seven (HL7), as recited in claim 6 (Application, paragraph 38).

The invention of independent claim 18 is a method of supplementing a medical record with information submitted by a patient (1). This method involves receiving from the patient (1) a machine-readable printed form (3) containing information about a health status of the patient (1). (Application, page 5, lines 19–23; page 8, lines 8–15). The printed form (3) is electronically scanned to convert the information to machine-processable data and communicate the data to a computer (9) (Application, page 9, line 17–page 10, line 2), and the machine-processable data is formatted with the computer (9) so that the data is in a form that may be communicated to an electronic medical record (15) that is personal to the patient (1). (Application, page 10, lines 3–8). The formatted data is communicated to an electronic medical record interface (17) and the information is added to the patient's personal medical record (Application, page 10, lines 3–12), wherein the patient's personal medical record contains patient-specific, clinical information regarding the patient's health, and presenting the information to a physician as part of the patient's personal electronic medical record (Application, page 10, lines 13–19).

The invention of claim 20 is a method of supplementing a medical record with

information submitted by a patient. The method includes receiving from the patient, prior to a visit with a physician, a machine-readable printed form filled out by the patient and containing information about a health status of the patient including the patient's medical history, environment, and symptoms (Application, page 8, lines 8–19). The printed form is electronically scanned to convert the information to machine-processable data and to communicate the data to a computer (Application, page 9, line 17–page 10, line 2). The machine-processable data is formatted with the computer so that the data is in the form of a Health Level Seven laboratory record, wherein the laboratory record includes the information from the printed form and information identifying an electronic medical record that is personal to the patient (Application, page 10, lines 2–8). This formatted data is communicated to an electronic medical record interface engine to automatically add the information to the patient's personal electronic medical record, wherein the patient's personal electronic medical record contains patient-specific, clinical information regarding the patient's health (Application, page 10, lines 9–12). The patient's personal electronic medical record is presented to the physician during the patient's visit with the physician, wherein the electronic medical record includes the information from the printed form. (Application, page 10, lines 13–19).

Appellant also notes that the page and line numbers cited above are for reference purposes only and should not be taken as a limitation on the support for, or scope of, the claimed subject matter. Support for the claimed subject matter may be found throughout the specification and drawings and the page and line numbers cited above merely refer to exemplary portions of the specification.

VI. Grounds of Rejection to be Reviewed on Appeal

A. Claim 1 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over Kimak, U.S. Patent Application No. 2005/0187794 A1, in view of Kraftson et al, U.S. Patent No. 6,151,581.

B. Claim 4 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over Kimak in view of Kraftson.

C. Claim 6 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over Kimak in view of Kraftson.

D. Claim 18 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over Kimak in view of Kraftson.

E. Claim 20 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over Kimak in view of Kraftson.

VII. Argument

A. Summary of Arguments

Appellants respectfully submit that the Examiner's rejections should not be sustained because:

1. Regarding the rejection of claims 1, 4, 6, 18 and 20, the Examiner has failed to identify a reason why a person of ordinary skill in the art would combine Kimak and Kraftson as proposed by the Examiner.

2. The Examiner has failed to identify a reference or combination of references that teach or suggest each limitation of claim 1.

3. The Examiner has failed to identify a reference or combination of references that teach or suggest each limitation of claim 4.

4. The Examiner has failed to identify a reference or combination of references that teach or suggest each limitation of claim 6.

5. The Examiner has failed to identify a reference or combination of references that teach or suggest each limitation of claim 18.

6. The Examiner has failed to identify a reference or combination of references that teach or suggest each limitation of claim 20.

B. Summary of U.S. Patent No. 6,151,581 issued to Kimak

Kimak discloses a system for managing pre-existing electronic medical records. Particularly, Kimak discloses a system for accessing or collecting electronic medical records stored on a variety of different private or public databases using a computer

network, and merging and de-duplicating the records for presentation to an end-use care provider. ¶¶ 3, 34. The system is used by registered point of service care providers to ascertain up-to-date immunization information for patients. ¶ 47.

Kimak discloses using the HL7 standard for communicating electronic medical record information, including immunization information, between remote servers and point of service care providers. *E.g.*, ¶¶ 5, 13, 34, 48, 51, and 57. Paragraph 34, for example, states that "[t]he HL7 is a standard by which communication between a main registry database and other private or public databases can transfer electronic medical records in a standardized form." (Emphasis added).

Notably, Kimak does not disclose use of a machine readable card; interfacing such a machine readable card with a scanning type machine to a patient's written answers to a data stream; arranging the data stream from such a scanning type machine into a defined data structure simulating the protocol structure from a party having authorization to export data to the patient's patient-specific electronic medical record; sending data originating from a machine readable card to an assigned location for importing into the patient's patient-specific electronic medical record; or presenting data originating from a machine readable card to a physician as part of the patient's personal electronic medical record; as recited in the application claims. In fact, Kimak does not contemplate any means for a patient to have input access to an electronic medical record, but rather manages electronic medical records created and maintained by care providers. ¶¶ 82, 119.

While Kimak does disclose use of the HL7 standard, Kimak discloses use of HL7 exclusively for communications between databases, not for communication between a scanning type machine and a database.

C. Summary of U.S. Patent No. 6,151,581 to Kraftson

Kraftson discloses a system and method for the "acquisition, management and processing of patient clinical information and patient satisfaction information received from

a group of physician practices to provide practice performance information." (Kraftson, col. 2, lines 52–56). Kraftson uses the information gathered from multiple practices to create statistical summaries of practice results, including effectiveness of treatment, patients' perception of the quality of the healthcare, and costs. (*Id.*, col. 5, lines 23–37, 52–62).

Kraftson discloses using machine-readable survey forms to collect information from both doctors and patients, scanning the survey forms, converting the information on the forms to a pre-determined data format, and storing the data in a database for further processing. (*Id.*, col. 5, lines 1–13; col. 6, lines 1–8). The survey forms are completed by the patient and the physician "during a treatment session at [the] physician's practice" or after the treatment session. Importantly, the patient's portion of the survey relates exclusively to satisfaction with the physician's services. (*Id.*, col. 6, line 3; col. 11, lines 15–17; col. 12, lines 14–24; tables 1A, 1B; FIGs. 2A–2C). Furthermore, the patient's portion of the survey is completely anonymous, therefore information submitted by a patient cannot be associated with that patient. (*See id.*, FIGs. 2B, 2C (illustrating patient surveys that include the declaration "THIS SURVEY IS TOTALLY ANONYMOUS")). Thus, Kraftson expressly discloses that the information collected by a patient is not associated with a particular patient, and therefore cannot be added to a patient specific electronic medical record.

The information submitted by the patient and the doctor is converted to "data records having a predetermined format." (*Id.*, col. 7, lines 8–9). Note that the information is converted to "data records," *not* medical records. The data records created by the system disclosed in Kraftson are entirely different than medical records. For example, the data records are created according to a format that facilitates statistical analysis of the information, such as storing prescription information in a sub-database separately from other elements of the information. (*Id.*, col. 7, lines 45–53). The data records are not used by a physician during a treatment session, and are never added to a patient's electronic medical record.

Thus, there are several notable differences between the method disclosed in Kraftson and the method of the application invention. First, the method of the application invention adds the information collected by the patient into the patient's patient-specific

electronic medical record for use during a doctor's visit, while the method of Kraftson stores the satisfaction information collected from the patient in anonymous data records for statistical analysis after the doctor's visit. Second, the method of the application invention collects health status information from the patient while the method of Kraftson collects satisfaction information from the patient. Third, the method of the application invention receives information from the patient prior to a doctor's visit, while the method of Kraftson receives information from the patient during or after the doctor's visit. Finally, the method of Kraftson increases the amount of information the doctor must record during a visit with the patient, while the method of the application invention reduces the amount of information the doctor must record during a visit with the patient.

Additional information regarding the Kraftson reference is provided below where appropriate. A discussion of the other cited references is also provided below where appropriate.

D. Obviousness

Obviousness can be a problematic basis for rejection because the Examiner, in deciding that a feature is obvious, has the benefit of the Applicant's disclosure as a blueprint and guide, whereas one with ordinary skill in the art would have no such guide, in which light even an exceedingly complex solution may seem easy or obvious. Furthermore, once an obviousness rejection has been made, the Applicant is in the exceedingly difficult position of having to prove a negative proposition (i.e., non-obviousness) in order to overcome the rejection. For these reasons, MPEP § 2142 places upon the Examiner the initial burden of establishing a *prima facie* case which requires, among other things, that there be identified some reason why a person of ordinary skill in the art would combine reference teachings. *KSR Int'l Co. v. Teleflex Inc.*, No. 04-1350, 2007 WL 1237837, 82 USPQ2d 1385 (S. Ct. April 30, 2007). If the Examiner fails to establish the requisite prima facie case, the rejection is improper and will be overturned. *In re Rijckaert*, 28 USPQ2d 1955, 1956 (Fed. Cir. 1993). Only if the Examiner's burden is met does the burden shift to the applicant to provide evidence to

refute the rejection.

In *KSR*, the Supreme Court reaffirmed that the Graham factors continue to define the inquiry controlling the obviousness determination. *KSR*, 2007 WL 1237837 at *7. The four Graham factors are (1) determining the scope and content of the prior art; (2) ascertaining the differences between the prior art and the claims at issue; (3) resolving the level of ordinary skill in the pertinent art; and (4) evaluating secondary consideration evidence, such as commercial success, long felt but unsolved needs, failure of others, etc. *Graham v. John Deere*, 383 U.S. 1, 17-18 (1966). Deputy Commissioner Facarino noted the reaffirmation of Graham and set forth other principles that govern the PTO's obviousness determination following *KSR* in her May 3, 2007, Memorandum to the Technology Center Directors ("Facarino Memorandum") for the present time.

Inventions generally rely upon previously known "building blocks" and will of necessity be combinations of what is already known. *KSR*, 2007 WL 1237837 at *14. Thus, "a patent composed of several elements is not proved obvious merely by demonstrating that each of its elements, was, independently, known in the prior art." Id.

Under the principles announced by the Supreme Court in *KSR*, it remains necessary for an examiner rejecting a claim under § 103 based upon a combination of prior art elements to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the prior art elements in the claimed manner. *KSR*, 2007 WL 1237837 at *14; Focarino Memo at 2. Mere conclusory statements cannot sustain an obviousness rejection; there must be "some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006), *cited with approval in KSR*, 2007 WL 1237837 at *13.

Taking into account the interrelated teachings of the prior art references; the effects of the demands known to the design community or marketplace; and the background knowledge possessed by a person having ordinary skill in the art, the Examiner should determine "whether there was an apparent reason to combine the known elements in the fashion claimed by the patent at issue. To facilitate review, this analysis should be made explicit." *KSR*, 2007 WL 1237837 at *13; Focarino Memo at 2.

Therefore, in formulating a rejection under 35 U.S.C. § 103(a) based upon

> a combination of prior art elements, it remains necessary to identify the reason why a person of ordinary skill in the art would have combined the prior art elements in the manner claimed.

Focarino Memo at 2.

It is improper to combine references where the references teach away from their combination. MPEP § 2145; *KSR*, 2007 WL 1237837 at *12. A reference teaches away when a person of ordinary skill, upon reading the reference, would be led in a direction divergent from the path that was taken by the applicant. *Kahn*, 441 F.3d at 990. When some references appear to suggest the combination, while others teach away from it, each reference has to be considered for its power to suggest solutions to a skilled artisan while still taking into account the degree to which one reference might accurately discredit another. *Medichem, S.A. v. Rolabo, S.L.*, 437 F.3d 1157, 1165 (Fed. Cir. 2006).

"The totality of the prior art must be considered, and proceeding contrary to accepted wisdom in the art is evidence of nonobviousness." MPEP § 2145, *citing In re Hedges*, 783 F.2d 1038 (Fed. Cir. 1986). Furthermore, known disadvantages in old devices and components that would discourage their development as new inventions are probative of nonobviousness. MPEP § 2145, *citing United States v. Adams*, 383 U.S. 39, 52 (1966).

A patent applicant can rebut a *prima facie* case of obviousness by showing "unexpected results," i.e., by showing that the claimed invention has some superior property or advantage that a person of ordinary skill in the relevant art would have found surprising or unexpected. *In re Soni*, 54 F.3d 746, 750 (Fed. Cir. 1995); *KSR*, 2007 WL 1237837 at * 12. "The basic principle behind this rule is straightforward – that which would have been surprising to a person of ordinary skill in a particular art would not have been obvious." *Soni*, 54 F.3d at 750.

In *KSR*, the Supreme Court recognized the need to avoid reading the teachings of the invention into the prior art and to be wary of the "distortion caused by hindsight bias" and "arguments reliant upon *ex post* reasoning." *KSR*, 2007 WL 1237837 at *16 (*citing Graham*, 383 U.S. at 36).

E. Regarding the rejection of claims 1, 4, 6, 18 and 20, the Examiner has failed to identify a reason why a person of ordinary skill in the art would combine Kimak and Kraftson as proposed by the Examiner.

In the Office Action dated February 28, 2007 ("OA"), claims 1, 4, 6, and 18–21 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Kimak in view of Kraftson. The Examiner asserted that at "the time of Applicant's invention, it would have been obvious to one of ordinary skill in the art to modify the method of Kimak with the teaching of Kraftson to use paper machine-readable questionnaires to obtain patient information." (OA, page 7). Appellant strongly disagrees.

The Examiner has failed to identify a reason why a person of ordinary skill in the art would combine Kimak with Kraftson as proposed by the Examiner. First, the system of Kraftson manages anonymous data records, while the system of Kimak manages patient-specific electronic medical records that are governed by laws restricting their use. As explained above in the sections titled "The Application Invention" and "Summary of U.S. Patent No. 6,151,581 to Kraftson," the data records managed by Kraftson are entirely different than the electronic medical records managed by Kimak. Electronic medical records, for example, are subject to laws and regulations such as HIPAA that govern their use and distribution. Kimak alludes to the restraints such laws and regulations place on the system, disclosing, for example, that point of service care providers must "enter the system through an approved method," and that providers can view data entered by other providers "provided proper disclosure forms have been obtained." (¶¶ 64, 76, *emphasis added*).

This is a significant distinction because the laws regulating the maintenance and use of electronic medical records are an obstacle to importing scan-card data into a patient-specific electronic medical record. Kimak discloses using the HL7 standard to communicate electronic medical record data between computer systems, and Kraftson discloses storing anonymous scan card data in anonymous data records, but the prior art does not contemplate using HL7 or any other means to communicate data from a card scanning machine to a patient-specific electronic medical record. As explained in the

Amendment dated June 20, 2006 (and supported by evidence submitted in an information disclosure statement accompanying the Amendment), for example, HL7 laboratory records are used for traditional laboratory tests, such as chemistry, hematology, and radiology, and—aside from Applicant's invention—are not used to import data from a scan-card machine into a patient's electronic medical record. Kraftson teaches that the records are anonymous so that "there is no danger of a patient's confidential information being inadvertently released," thus teaching away from the use of patient-specific data records. (Col. 12, lines 55–57). Kimak, in contrast, must use patient-specific electronic medical records, otherwise the records would be of no use to a physician viewing them. Because the system of Kimak is incompatible with the system of Kraftson, a person skilled in this art would have not reason to combine Kimak and Kraftson as proposed by the Examiner.

Second, even if the privacy laws and regulations associated with patient-specific electronic medical records could somehow be overcome to combine Kimak with Kraftson, the system of Kraftson never associates information collected from patients or physicians with particular patients or physicians, but rather collects and maintains the information anonymously. Therefore, it would have no use with Kimak because Kimak must be able to associate patient information with particular patients to be of any use. (*See, e.g.*, Kimak, ¶ 94, FIG. 8). Furthermore, the system of Kraftson teaches away from identifying patient or physician information with particular patients or physicians because Kraftson uses the information for statistical purposes. (Kraftson, col. 5, lines 23–38).

Third, the system of Kimak does not import information into a patient's electronic medical record, as recited in claim 1, but rather uses electronic medical records already created by physicians. The system disclosed in Kimak gleans information from the medical records to present to users, and even stores entire copies of medical records on physicians' computer systems, but does not import information into electronic medical records. Therefore, Kimak and Kraftson considered in combination fail to teach any form of importing information received from a patient to a patient-specific electronic medical record, much less "arranging the data stream [from a scanning type machine] into a defined data structure simulating the protocol structure from a party having authorization to export data to the patient's patient-specific electronic medical record . . ."

Fourth, the system of Kimak does not receive information directly from users, only from remote servers (¶ 66). Kimak is interested only in the treatment history—in this case immunizations—which is information obtained from physicians, not from patients. Because the system disclosed in Kimak is intended and designed for use only with treatment history data obtained from remote computer systems, there is no suggestion or motivation to modify Kimak as proposed in the Office Action to receive data directly from a patient via a machine-readable questionnaire.

Finally, neither Kraftson nor Kimak discloses how the information from the patient survey forms of Kraftson could be arranged "into a defined data structure simulating the protocol structure from a party having authorization to export data to the patient's" electronic medical record, as recited in claim 1.

In support of her assertion that "it would have been obvious to one of ordinary skill in the art to modify the method of Kimak with the teachings of Kraftson to use paper machine-readable questionnaires to obtain patient information," the Examiner states that "[o]ne would have been motivated to include this feature to provide a user friendly, easily accessible manner for physicians to monitor patients and their practices, without disrupting the physician's practice." (OA, page 7). This is exactly the type of "conclusory statement" the Supreme Court recently rejected as a grounds for forming a sustainable obviousness rejection, and the Examiner's assertion clearly falls short of the required "articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006), *cited with approval in KSR*, 2007 WL 1237837 at *13. The Examiner fails, for example, to identify why a person skilled in this art would believe that the proposed combination would result in the alleged benefits.

For at least these reasons, a person of ordinary skill in this art would have no reason to combine Kimak and Kraftson as proposed by the Examiner.

F. Regarding the rejection of claim 1 under 35 U.S.C. § 103(a) over Kimak in view of Kraftson, Kimak and Kraftson do not teach or suggest each limitation of claim 1.

Regarding the rejection of claim 1, the Examiner has failed to establish the requisite *prima facie* case of obviousness because the Examiner has failed to identify a reference or combination of references that teach or suggest each limitation of claim 1. Even if Kimak is indiscriminately combined with Kraftson, for example, the combination does not teach or suggest "sending the formatted data to an assigned location for importing into the patient's patient-specific electronic medical record, wherein the patient's electronic medical record contains patient-specific, clinical information regarding the patient's health," as recited in claim 1.

The system of Kimak includes "an electronic medical record *registry* system" (¶ 33, emphasis added), wherein the system accesses electronic medical records from "a plurality of medical service provider databases" and presents information from those records to "registered point of service care providers" as a complete medical history of the patient. (Kimak, ¶¶ 47, 74, 75; FIG. 3). While Kimak discloses "merging" medical records (¶ 12), this merging operation involves merging information from multiple medical records into a single "view" or user interface element, and does not involve creating a new medical record. Kimak expressly discloses, for example, that "the merging does not result in creation of a storage location for a new record." (¶ 35). Moreover, when electronic medical records are communicated to the main registry database, the medical records are sent in their entirety and replaced by new, updated records when necessary. (¶¶ 77–81). Thus, information is never imported into a medical record, as recited in claim 1.

For at least this reason, Kimak does not teach or suggest "sending the formatted data to an assigned location for importing into the patient's patient-specific electronic medical record, wherein the patient's electronic medical record contains patient-specific, clinical information regarding the patient's health," as recited in claim 1.

Kraftson also fails to teach or suggest "sending the formatted data to an assigned location for importing into the patient's patient-specific electronic medical record, wherein the patient's electronic medical record contains patient-specific, clinical information

regarding the patient's health." The invention disclosed in Kraftson does not deal with electronic medical records that contain patient-specific, clinical information regarding the patient's health because, for example, the information gathered via the survey is stored in an anonymous database and used exclusively for statistical analyses based on patient satisfaction.

Column 6, lines 10–18 of Kraftson read:

> The System further includes a Data Analysis Processor 108 for analyzing the Physician/Patient/Management information according to selected data analysis packages such as Statistical Package for the Social Sciences (SPSS) or SAS, a Report Generation Module 110 for generating formatted reports containing results determined by the Data Analysis Processor 108, and an Outcomes Measurement Module 112 for recording and tracking performance of the System.

As can be seen, this section discloses analyzing information and generating a "formatted report," but fails to even suggest importing data "into the patient's patient-specific electronic medical record," as recited in claim 1. As explained above, a patient's electronic medical record is not a report containing results of an automated data analysis, but rather a private record containing that patient's personal, patient-specific, medical information that is viewable by a physician at the time the patient receives care from the physician.

Furthermore, Kraftson expressly teaches that the system disclosed therein generates two kinds of reports: 1) "a periodic report which summarizes general information about a quality level of the practice," and 2) "real time reports in response to physician queries" such as where a physician needs "information comparing the historical data concerning satisfaction of patient treatment in order for the physician to determine where a recently implemented change in treatment regimen improves or decreases patient satisfaction." (Kraftson, col. 8, lines 39–63, *emphasis added*). These reports are clearly not patient-specific electronic medical records viewable at the time of care, which is further evidenced by Kraftson's disclosure that physicians must "dial up" a report generation module, and receive "periodic practice reports" or "printed reports." (*Id.*, col. 5, lines 12–16).

It would not have been obvious to one of ordinary skill in the art to modify Kraftson to send "formatted data to an assigned location for importing into the patient's patient-

specific electronic medical record, wherein the patient's electronic medical record contains patient-specific, clinical information regarding the patient's health," as recited in claim 1. For example, adding information to a patient's medical record must be done in a manner that conforms with the privacy requirements described above, which, prior to Applicant's invention, was done manually with software accessible only by physicians and trained medical staff. Furthermore, Kraftson expressly teaches that the information collected from patients is anonymous satisfaction information, and that automated analyses of the information are shared among physician groups. These teachings are incompatible with the use of electronic medical records containing patient-specific, clinical information regarding the patient's health, which are subject to HIPAA and other privacy laws and regulations.

For at least the reasons set forth above, neither Kimak nor Kraftson teaches or suggests "sending the formatted data to an assigned location for importing into the patient's patient-specific electronic medical record, wherein the patient's electronic medical record contains patient-specific, clinical information regarding the patient's health," as recited in claim 1. Furthermore, Kimak and Kraftson considered in combination also fail to teach or suggest this element of claim 1. Kimak teaches sharing existing medical records between systems to create a medical history of one or more patients, but does not teach or suggest importing data into a patient's electronic medical record. Kraftson teaches away from using electronic medical records altogether by teaching using other forms of records that non-patient specific information and that are anonymous.

G. Regarding the rejection of claim 4 under 35 U.S.C. § 103(a) over Kimak in view of Kraftson, Kimak and Kraftson do not teach or suggest each limitation of claim 4.

Claim 4 depends from claim 1, and recites "wherein the machine readable questionnaire includes questions concerning the systems making up the human body with designated locations for patient responses." All of the arguments set forth above in relation to the rejection of claim 1 also apply to the rejection of claim 4. Additionally, neither Kimak nor Kraftson, considered alone or in combination, teach or suggest the additional

limitations recited in claim 4.

Kimak does not involve a machine-readable questionnaire, and the survey-forms disclosed in Kraftson do not include questions concerning "the systems making up the human body," but rather satisfaction with the physician's services. Because the survey-forms are anonymous and relate to patient satisfaction, a person skilled in the art would have no reason to modify Kimak to use machine readable questionnaires including "questions concerning the systems making up the human body with designated locations for patient responses."

H. Regarding the rejection of claim 6 under 35 U.S.C. § 103(a) over Kimak in view of Kraftson, Kimak and Kraftson do not teach or suggest each limitation of claims 6.

Claim 6 depends from claim 1, and recites "further comprising the step of converting and arranging the data stream to a defined set of data structures simulating the protocol of Health Level Seven (HL7)." All of the arguments set forth above in relation to the rejection of claim 1 also apply to the rejection of claim 6. Additionally, neither Kimak nor Kraftson, considered alone or in combination, teach or suggest the additional limitations recited in claim 4 because the prior art teaches using HL7 laboratory records exclusively for traditional laboratory tests, such as blood tests, and does not contemplate using HL7 laboratory records to communicate information relating to the patient's "medical history, environment, and symptoms." Furthermore, a skilled artisan will recognize that HL7 cannot be used with the system taught by Kraftson because HL7 requires the use of patient-specific identifiers, which cannot be present in the anonymous records disclosed by Kraftson.

Applicant submitted various references in an Information Disclosure Statement on April 3, 2006, that indicate HL7 laboratory records have been used exclusively for traditional laboratory tests. According to these articles, the healthcare industry is standardizing the format in which data is communicated from laboratories to health care providers, such as hospitals and doctors' offices, and to that end has created the Logical Observation Identifier Names and Codes (LOINC) database. The LOINC database is a

list of tests and matching codes used to identify each test. The following discussion shows that the laboratory tests included in the LOINC database are strictly traditional laboratory tests, such as blood tests, urine tests, and so forth, illustrating that the prior art did not contemplate—and indeed still does not contemplate—including medical history, symptom, and environment information in HL7 laboratory records.

The article entitled "LOINC, a Universal Standard for Identifying Laboratory Observations: A 5-Year Update" by McDonald et al. ("McDonald"), explains that the

> "Logical Observation Identifier Names and Codes (LOINC) database provides a universal code system for reporting laboratory and other clinical observations. Its purpose is to identify observations in electronic messages such as Health Level Seven (HL7) observation messages, so that when hospitals, health maintenance organizations, pharmaceutical manufacturers, researchers, and public health departments receive such messages from multiple sources, they can automatically file the results in the right slots of their medical records, research, and/or public health systems."

(McDonald, page 2, emphasis added).

Thus, the LOINC is a universal standard for formatting laboratory records. McDonald further explains that

> "[a]s of July 2002, the LOINC database carried records for more than 30,000 different observations. Each record carries the formal six-part LOINC name; the LOINC code, a number with a check digit (see Table 1); the observation class (e.g., chemistry, hematology, and radiology); related names (to assist searches of the database); and other attributes."

(McDonald, page 5, emphasis added).

Therefore, the LOINC database is a standard for communicating laboratory records, such as HL7 laboratory records, to hospitals from laboratories and relates only to traditional laboratory test measurements, such as "chemistry, hematology, and radiology."

The article entitled "Logical observation identifier names and codes (LOINC) database: a public use set of codes and names for electronic reporting of clinical laboratory test results" by Forrey et al. ("Forrey"), also discusses the character and purpose of the LOINC database. Forrey explains that the LOINC database provides a universal set of test identifiers that all laboratories may use to electronically communicate test results from laboratories to the laboratories' clients via standards such as HL7. (Forrey, page 81).

Forrey explains that "each LOINC observation name identifies a distinct laboratory

observation" and includes up to six parts, where the six parts are listed in table 1. (Forrey, page 83). One of the parts listed in table 1 is the "[k]ind of property measured or observed." On page 84, Forrey explains that "[a] selected list of the most common LOINC kinds of properties is shown in Table 3." Table 3 lists the following properties: substance concentration; catalytic concentration; catalytic content; mass concentration; mass content; mass concentration ratio; mass rate, for excretions; and volume rate, for clearances. These properties clearly related only to traditional laboratory tests. This is but one example.

In summary, Forrey and McDonald show that the LOINC database of laboratory test codes is limited to traditional laboratory tests, such as chemical, hematological, and radiological tests. Because the LOINC database is intended to include a comprehensive or nearly comprehensive list of tests communicated between laboratories and healthcare providers, the prior art clearly does not contemplate formatting information relating to medical history, environment, and symptoms into an HL7 laboratory record and communicating the record to an electronic medical record interface engine, as recited in claim 6.

Furthermore, these various references relating to the LOINC database demonstrate that the prior art did not contemplate formatting data received from a patient's questionnaire so that the data is in the form of an HL7 laboratory record. Rather, the references show that only data derived in a laboratory will be so formatted.

I. Regarding the rejection of claim 18 under 35 U.S.C. § 103(a) over Kimak in view of Kraftson, Kimak and Kraftson do not teach or suggest each limitation of claim 18.

Claim 18 recites some limitations that are similar to those of claim 1, therefore the arguments set forth above in relation to the rejection of claim 1 also apply to the rejection of claim 18. Claim 18 further recites "presenting the information to a physician as part of the patient's personal electronic medical record."

Kimak does not disclose the use of forms to collect patient information, as explained above, much less "communicating the [scanned and] formatted data to an electronic

medical record interface and adding the information to the patient's personal medical record" and "presenting the information to a physician as part of the patient's electronic medical record," as recited in claim 18.

Kraftson also fails to teach or suggest these limitations. Kraftson, for example, discloses use of anonymous survey forms to gather information about satisfaction with a physician's services. (*See supra*, page 8). An anonymous survey form cannot be associated with a "patient's personal medical record [containing] patient-specific, clinical information," and information about a patient's satisfaction with a physician's services cannot be presented to the physician before the physician renders the services.

Finally, the combination of Kimak and Kraftson does not teach or suggest these limitations. Kimak discloses a registry system for gathering information from existing electronic medical records stored on various computer systems, while Kraftson discloses a system for collecting anonymous patient survey information relating to patient satisfaction. Thus, the teachings of Kimak and Kraftson considered in combination fail to teach or suggest "presenting the information to a physician as part of the patient's electronic medical record," as recited in claim 18.

For at least these reasons, neither Kimak nor Kraftson, considered singly or in combination, teaches or suggests each element of claim 18, including "presenting the information to a physician as part of the patient's personal electronic medical record."

J. Regarding the rejection of claim 20 under 35 U.S.C. § 103(a) over Kimak in view of Kraftson, Kimak and Kraftson do not teach or suggest each limitation of claim 20.

Claim 20 recites some limitations that are similar to those of claims 1, 6, and 18, therefore the arguments set forth above in relation to the rejection of claims 1, 6, and 18 also apply to the rejection of claim 20.

Claim 20 recites "receiving from the patient, prior to a visit with the physician, a machine-readable printed form filled out by the patient and containing information about a health status of the patient including the patient's medical history, environment, and symptoms." Neither Kimak nor Kraftson, considered singly or in combination, teaches or

suggests this limitation. As explained above, Kimak does not disclose the use of machine-readable printed forms at all. Kraftson discloses the use of "machine-readable surveys," but discloses use of anonymous survey forms to gather information about satisfaction with a physician's services (*See supra*, page 8), not a "health status of the patient including the patient's medical history, environment, and symptoms" as recited in claim 20. Furthermore, the surveys disclosed in Kraftson cannot be received prior to a visit with a physician because information about satisfaction with a physician's services cannot be provided prior to the rendering of those services.

Claim 20 further recites "electronically scanning the printed form to convert the information to machine-processable data and to communicate the data to a computer." It should be noted that the printed form scanned in this step is the form filled out by the patient with a "health status of the patient including the patient's medical history, environment, and symptoms" and received from the patient prior to a visit with the physician. Neither Kimak nor Kraftson discloses receiving such a form from a patient, much less electronically scanning the form as recited in this step of claim 20. As explained above, Kraftson discloses using anonymous survey forms with patient satisfaction information, and a person skilled in this art would have no reason to modify Kraftson to include the type of form recited in claim 20 because of the obstacles, such as HIPPA, explained above.

Claim 20 further recites "formatting the machine-processable data with the computer so that the data is in the form of a Health Level Seven laboratory record, wherein the laboratory record includes the information form the printed form and information identifying an electronic medical record that is personal to the patient." It should be noted that the machine-processable data that is formatted in this step includes the "health status of the patient including the patient's medical history, environment, and symptoms" received from the patient on the printed form. Prior to appellant's invention, formatting data received from a patient in this manner so that the data is in the form of a Health Level Seven laboratory record was never contemplated in the art because, for example, the Health Level Seven standard was not developed, nor has it been used (other than Appellant's invention) for this purpose. The discussion set forth above and the references cited herein clearly

established that the claim invention represents a novel use of the HL7 standard that has never even been contemplated by others skilled in this art.

Claim 20 further recites "presenting the information to a physician as part of the patient's personal electronic medical record." Neither Kimak nor Kraftson, considered singly or in combination, teaches or suggests each element of claim 20, including "presenting the information to a physician as part of the patient's personal electronic medical record."

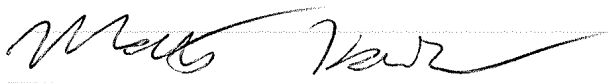
For at least these reasons, as well as for reasons set forth above in relation to the rejections 1, 6, and 18, Kimak and Kraftson, considered singly or in combination, fail to teach or suggest each element of claim 20.

K. Conclusion

For at least the reasons set forth above, the Examiner has failed to identify a reason why a person of ordinary skill in the art would combine Kimak and Kraftson. The Examiner has further failed to identify a reference or combination of references that teach or suggest each limitation of claim 1, claim 4, claim 6, claim 18, and claim 20.

Accordingly, reversal of the Examiner's rejections is proper, and such favorable action is solicited.

Respectfully submitted,

By 

Matthew P. Harlow, Reg. No. 52,994
HOVEY WILLIAMS LLP
2405 Grand Boulevard, Suite 400
Kansas City, MO 64108
(816) 474-9050

ATTORNEYS FOR APPELLANT

VIII. Claims Appendix

1. A process of allowing a patient to have limited input access to their electronic medical record, the method comprising the steps of:

a) providing the patient with a machine readable card including a questionnaire concerning the patient's medical history, environment, symptoms, or other pertinent information for answering by the patient;

b) interfacing the machine readable card with a scanning type machine to convert the patient's written answers to a data stream;

c) arranging the data stream into a defined data structure simulating the protocol structure from a party having authorization to export data to the patient's patient-specific electronic medical record; and

d) sending the formatted data to an assigned location for importing into the patient's patient-specific electronic medical record, wherein the patient's electronic medical record contains patient-specific, clinical information regarding the patient's health.

2. The process of claim 1, further comprising the step of forming a basic patient medical record in a computer through entry of information using a keyboard by a professional staff member.

3. (Cancelled)

4. The process of claim 1 wherein the machine readable questionnaire includes questions concerning the systems making up the human body with designated locations for patient responses.

5. The process of claim 1 wherein the step of interfacing the machine readable card with the scanning type machine is accomplished by a member of the clinical staff.

6. The process of claim 1, further comprising the step of converting and arranging the data stream to a defined set of data structures simulating the protocol of Health Level Seven (HL7).

7. The process of claim 1, further comprising the step of arranging the data stream into a defined data structure according to a protocol of ASTM (American Society for Testing and Materials).

8. (Cancelled)

9. The process of claim 1, further comprising the step of receiving the formatted data with an interface engine and sending it to a database containing the patient's electronic medical record.

10. The process of claim 2 wherein the computer is a standard PC microcomputer and the keyboard is compatible with the computer.

11. The process of claim 4 wherein the machine readable card is a paper answer sheet comprised of questions with designated areas for patient responses.

12. (Cancelled)

13. The process of claim 9 wherein said database is any database that accepts HL7 or ASTM messaging.

14. The process of claim 6 wherein the step of arranging the data stream into a defined set of data structures simulating the protocol from a party having authorization to export data into the patient's electronic medical record includes the step of accepting the data stream from the scanning type machine and arranging the data stream into a defined set of data structures simulating the HL7 specification.

15–16. (Cancelled)

17. The process of claim 2 wherein the computer is a standard PC, with at least 32 megabytes of hard drive space and a processor capable of operating at 100 MHz.

18. A method of supplementing a medical record with information submitted by a patient, the method comprising the steps of:

receiving from the patient a machine-readable printed form containing information about a health status of the patient;

electronically scanning the printed form to convert the information to machine-processable data and communicate the data to a computer;

formatting the machine-processable data with the computer so that the data is in a form that may be communicated to an electronic medical record that is personal to the patient;

communicating the formatted data to an electronic medical record interface and adding the information to the patient's personal medical record, wherein the patient's personal medical record contains patient-specific, clinical information regarding the patient's health; and

presenting the information to a physician as part of the patient's personal electronic medical record.

19. The method as set forth in claim 18, further comprising the steps of:

mailing the form to the patient prior to the appointment; and

presenting the patient's electronic medical record to the physician, including the information from the printed form, before the patient visits the doctor to apprise the physician of the patient's health status in the patient's absence.

20. A method of supplementing a medical record with information submitted by a patient, the method comprising the steps of:

receiving from the patient, prior to a visit with a physician, a machine-readable printed form filled out by the patient and containing information about a health status of the patient including the patient's medical history, environment, and symptoms;

electronically scanning the printed form to convert the information to machine-processable data and to communicate the data to a computer;

formatting the machine-processable data with the computer so that the data is in the form of a Health Level Seven laboratory record, wherein the laboratory record includes the information from the printed form and information identifying an electronic medical record that is personal to the patient;

communicating the formatted data to an electronic medical record interface engine to automatically add the information to the patient's personal electronic medical record, wherein the patient's personal electronic medical record contains patient-specific, clinical information regarding the patient's health; and

presenting the patient's personal electronic medical record to the physician during the patient's visit with the physician, wherein the electronic medical record includes the information from the printed form.

21. The method as set forth in claim 19, further comprising the steps of:

mailing the form to the patient prior to the appointment; and

presenting the patient's electronic medical record to the physician, including the information from the printed form, prior to the visit to inform the physician of the patient's health status.

IX. Evidence appendix

None.

X. Related proceedings appendix

None.